## REMARKS

This paper is filed in response to the Office Action mailed January 8, 2007. Claims 10, 12 to 14, 21, 22 and 40 to 68 stand withdrawn for consideration as directed to a non-elected invention. Claims 4, 74 and 76 have been cancelled herein without prejudice. Applicants maintain the right to prosecute the cancelled claims in any related application claiming the benefit of priority of the subject application. Accordingly, claims 1 to 3, 6, 7, 11, 15 to 18, 23 to 31, 33 to 39, 69 to 73 and 75 are under consideration.

*Regarding the Amendments*

The amendments to the claims are supported throughout the specification. In particular, the amendments to claims 1, 15, 16, 29, 31 73 and 75 to recite one or more of "pulmonary tissue, respiratory tract, spleen, lymph node or lymph vessel" is supported, for example, by originally filed claim 4, and in the specification, for example, at page 4, lines 5-11; page 13, lines 30-34; and page 14, lines 6-24. Accordingly, as the amendments to the claims are supported by the specification no new matter has been added and entry thereof is respectfully requested.

*Regarding the Declaration*

The objection to the Oath or Declaration has been withdrawn. Accordingly, the executed Declaration, filed under 35 U.S.C. 25 and 37 C.F.R. §1.68, is not defective.

I. REJECTION UNDER 35 U.S.C. §112, first paragraph

The rejection of claims 74 and 76 under 35 U.S.C. §112, first paragraph as allegedly lacking enablement is respectfully traversed. Allegedly, claims 74 and 76 are not adequately enabled, wherein inflammation is prevented or eliminated.

Claims 74 and 76 are adequately enabled under 35 U.S.C. §112, first paragraph. Nevertheless, solely in order to further prosecution of the application and without acquiescing to the propriety of the rejection, claims 74 and 76 have been cancelled without prejudice. Accordingly, the rejection under 35 U.S.C. §112, first paragraph is moot.

II. THE DECLARATION UNDER 37 C.F.R. §1.131 EXECUTED BY THE INVENTORS

Allegedly the Declaration under 37 C.F.R. §1.131 filed March 23, 2006, is considered deficient due to conception or reduction to practice taking place in this country or a NAFTA or WTO member country. The evidence submitted with the Declaration allegedly is also insufficient to establish diligence from prior to the December 18, 2001 priority provisional application filing date of the cited Arndt *et al.* publication (U.S. Publication No. 2004/0009174) to either a constructive or actual reduction to practice.

Submitted herewith is a Supplemental Declaration under 37 C.F.R. §1.131 executed by the inventors of the application. In the Supplemental Declaration, it is stated that the studies relied upon that establish conception and diligence occurred in the United States (paragraph 6).

Applicants note that the Supplemental Declaration is accompanied by copies of laboratory notebook pages evidencing conception and diligence from prior to the December 18, 2001 priority application filing date of the Arndt *et al.* publication up to the September 11, 2002 filing of the priority provisional application (60/410,534). However, the submission of these laboratory notebook pages is not to be construed as an admission that the invention was not actually reduced to practice prior to December 18, 2001. Applicants therefore reserve the right to assert conception and actual reduction to practice prior to December 18, 2001. Furthermore, the laboratory notebook pages submitted herewith are representative of studies performed during the relevant time period and are not to be construed as limiting Applicants solely to these particular laboratory notebook pages as evidence of conception and diligence.

Accompanying the Supplemental Declaration is evidence of conception of claims 1 to 4, 6, 7, 11, 15 to 18, 23 to 31, 33 to 39 and 69 to 76, supplied in the form of copies of four pages from laboratory notebooks (Exhibit A, dates redacted), each of which is labeled A1-A4. Exhibit A is identical to previously filed Exhibit A submitted with the Declaration under 37 C.F.R. §1.131, which was filed March 23, 2006. The contents of Exhibit A is discussed in the Supplemental Declaration at paragraphs 8-10.

Also accompanying the Supplemental Declaration is evidence of diligence for claims 1 to 4, 6, 7, 11, 15 to 18, 23 to 31 and 69 to 76 from prior to December 18, 2001, up until the September 11, 2002 filing of provisional patent application serial no. 60/410,534, supplied in the form of copies of pages from laboratory notebooks, denoted Exhibits B-G (dates redacted). Each

of Exhibits B-G include one or more representative studies performed during a time period prior to December 18, 2001, and up to September 11, 2002. Exhibit B, pages B1-B5; Exhibit C, pages C1-C12; Exhibit D, pages D1-D7; Exhibit E, pages E1-E24; Exhibit F, pages F1-F16; and Exhibit G, pages G1-G17. Exhibits B-G are discussed in the Supplemental Declaration at paragraphs 11-18.

Applicants respectfully refer the Examiner to the Supplemental Declaration under 37 C.F.R. §1.131 and accompanying laboratory notebook pages submitted herewith as Exhibits A-G. In view of the Supplemental Declaration under 37 C.F.R. §1.131 and accompanying Exhibits A-G, claims 1 to 3, 6, 7, 11, 15 to 18, 23 to 31, 33 to 39, 69 to 73 and 75 were conceived prior to the December 18, 2001, filing date of the Arndt *et al.* provisional application (serial no. 60/341,453), and the inventors were diligent up to the September 11, 2002 filing of the priority provisional application (60/410,534). Accordingly, Applicants respectfully request reconsideration of the rejections under 35 U.S.C. §§102(e) and 103(a).

REJECTIONS UNDER 35 U.S.C. §§102(e) and 103(a)

The rejection of claims 1 to 4, 6, 7, 15 to 18, 23 to 31, 33 to 39 and 69 to 76 under 35 U.S.C. §102(e) as allegedly anticipated by Arndt *et al.* (U.S. Patent Publication No. 2004/0009174) is respectfully traversed. The rejection has been maintained in view of the deficiencies of the Declaration filed March 23, 2006 discussed above. Allegedly, the Declarations under 37 C.F.R. §1.131 and 37 C.F.R. §1.132 are not of sufficient scope relative to the scope of the claims and of Arndt *et al.*

Claims 4, 74 and 76 have been cancelled herein without prejudice solely in order to further prosecution of the application and without acquiescing to the propriety of the rejection. Accordingly, the rejection of these claims is moot, and will only be addressed insofar as it may be applied to claims 1 to 3, 6, 7, 15 to 18, 23 to 31, 33 to 39, 69 to 73.

Applicants first respectfully point out that in order to antedate a cited reference by way of a 37 Declaration under C.F.R. §1.131, "antedating affidavits must contain facts showing a completion of 'the invention' commensurate with the extent the invention is shown in the reference, whether or not it be a showing of the identical disclosure of the reference." *In re Wakefield and Foster*, 422 F.2d 897 (C.C.P.A. 1970), citing *In re Clarke*, 356 F.2d 987, 991,

(C.C.P.A. 1966). Thus, Applicants need only show evidence of prior invention for claimed subject matter commensurate with what is described in the Arndt *et al.* priority provisional application.

The Arndt *et al.* priority provisional application at most shows that OX40L is expressed on smooth muscle cells. Arndt *et al.* proposes to treat inflammatory disease of smooth muscle tissue, particularly airway smooth muscle, and asthma (Field of the Invention), with an agent that inhibits or blocks interaction between OX40 and OX40L (Summary).

Turning to Exhibit A submitted herewith, the inventors conclude the data indicate that anti-OX40L antibody reduces clinical indicia of asthma and that anti-OX40L antibody reduces eosinophil and lymphocyte infiltration of lung associated with asthma (Supplemental Declaration under 37 C.F.R. §1.131, paragraphs 9 and 10). Consequently, the data in Exhibit A is commensurate with the extent of the invention shown in the Arndt *et al.* priority provisional application as applied against claims 1 to 4, 6, 7, 15 to 18, 23 to 31, 33 to 39 and 69 to 76 under 35 U.S.C. §102(e). Furthermore, the accompanying laboratory notebook pages (Exhibits B-G) submitted herewith evidence diligence up to the September 11, 2002 filing of the priority provisional application. Accordingly, Arndt *et al.* (U.S. Patent Publication No. 2004/0009174) is not available as prior art under 35 U.S.C. §102(e) against claims 1 to 4, 6, 7, 15 to 18, 23 to 31, 33 to 39 and 69 to 76.

Furthermore, a reference in order to be properly cited under 35 U.S.C. §102, must contain "an enabling disclosure." *In re Hoeksema*, 399 F.2d 269 (C.C.P.A. 1968). The court's position is that "[t]he disclosure in an assertedly anticipating reference must be adequate to enable possession of the desired subject matter. It is insufficient to name or describe the desired subject matter, if it cannot be produced without undue experimentation." *Elan Pharm., Inc. v. Mayo Foundation for Medical and Educational Research*, 346 F.3d 1051, 1054 (Fed. Cir. 2003).

Here, the Arndt *et al.* priority provisional application fails to describe any data indicating that a recall immune response can be reduced or inhibited, or that a symptom associated with a secondary or subsequent immune response to an antigen can be alleviated or ameliorated, such as asthma, as claimed. As discussed above, the Arndt *et al.* priority provisional application at most shows that OX40L is expressed on smooth muscle cells, and proposes to treat inflammatory disease of smooth muscle tissue, particularly airway smooth muscle, and asthma using an agent

that inhibits or blocks interaction between OX40 and OX40L. However, the Arndt *et al.* priority provisional application fails to describe any data to indicate that an antibody that specifically binds to OX40L would reduce or inhibit any recall immune response, let alone a recall immune response in pulmonary tissue, respiratory tract, spleen, lymph node or lymph vessel. The Arndt *et al.* priority provisional application also fails to show any difference in OX40L expression in asthmatics as compared to non-asthmatics on airway smooth muscle cells (Figures 1 and 3), making it speculation at best that an agent that inhibits or blocks interaction between OX40 and OX40L can be used to treat asthma.

Furthermore, the Patent Office will appreciate that there are thousands of proteins expressed on smooth muscle cells, and expressed within the lung and respiratory tract. Mere expression of a particular protein among thousands does not translate into a functional role. In the absence of functional data in the Arndt *et al.* priority provisional application it is at best speculation that an antibody that specifically binds to OX40L would reduce or inhibit any recall immune response, let alone a recall immune response in pulmonary tissue, respiratory tract, spleen, lymph node or lymph vessel. Moreover, the Arndt *et al.* priority provisional application fails to even mention spleen, lymph node or lymph vessel.

Thus, in view of the foregoing deficiencies, it cannot be objectively be said that the Arndt *et al.* priority provisional application enables or teaches each and every element of claims 1 to 4, 6, 7, 15 to 18, 23 to 31, 33 to 39 and 69 to 76. Consequently, the rejection under 35 U.S.C. §102(e) over Arndt *et al.* (U.S. Patent Publication No. 2004/0009174) must be withdrawn.

The rejection of claims 1 and 11 under 35 U.S.C. §103(a) as allegedly unpatentable over Arndt *et al.* in view of Owens *et al.* (J. Immunol. Methods 168:149 (1994)) is respectfully traversed. Allegedly, claims 1 and 11 would have been obvious at the time of the invention to one of ordinary skill in the art in view of Arndt *et al.* and Owens *et al.*

Claims 1 and 11 would not have been obvious in view of Arndt *et al.* and Owens *et al.* at the time of the invention. For the reasons discussed above, the data in Exhibit A is commensurate in scope with the extent of the invention in the Arndt *et al.* priority provisional application as applied against claims 1 and 11 under 35 U.S.C. §103(a). Furthermore, the accompanying laboratory notebook pages (Exhibits B-G) submitted herewith evidence diligence

up to the September 11, 2002 filing of the priority provisional application. Accordingly, Arndt *et al.* (U.S. Patent Publication No. 2004/0009174) is not available as prior art under 35 U.S.C. §103(a) against claims 1 and 11.

Owens *et al.* (J. Immunol. Methods 168:149 (1994)) fail to teach or suggest each and every element of claims 1 and 11. Consequently, the rejection of claims 1 and 11 under 35 U.S.C. §103(a) must be withdrawn.

## CONCLUSION

In summary, for the reasons set forth herein, Applicants maintain that claims 1 to 3, 6, 7, 11, 15 to 18, 23 to 31, 33 to 39, 69 to 73 and 75 clearly and patentably define the invention, respectfully request that the Examiner reconsider the various grounds set forth in the Office Action, and respectfully request the allowance of the claims which are now pending.

If the Examiner would like to discuss any of the issues raised in the Office Action, Applicant's representative can be reached at (858) 509-4065.

Please charge any fees associated with the submission of this paper to Deposit Account Number 03-3975. The Commissioner for Patents is also authorized to credit any over payments to the above-referenced Deposit Account.

Respectfully submitted,

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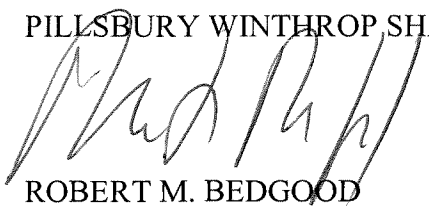

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